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BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			PENDLETON, BRIAN T	
			ART UNIT	PAPER NUMBER
			2644	4

DATE MAILED: 07/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/002,173

Applicant(s)

COHEN ET AL.

Examiner

Brian T. Pendleton

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Priority***

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

***Drawings***

2. The drawings are objected to because of inconsistencies between the specification and the reference numbers in the drawings. Specifically, visual display module 14 is to be provided with a liquid crystal display (LCD) device 15, however, figure 1 does not illustrate that feature. It appears that reference number 15 indicates the body site B of a patient. In addition, the drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "13" has been used to designate both an acoustic earphone in figure 1 and the body site B for auscultation in figure 5. Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the

changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Specification***

3. The disclosure is objected to because of the following informalities: Switch 29 exemplified in figure 6 is referred to as "switch 28" in the specification, page 13.

Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 1 and 3** are rejected under 35 U.S.C. 102(b) as being anticipated by Marshall et al, US Patent 3,858,005 (hereafter referenced as Marshall).

Regarding **claim 1**, Marshall discloses a stethoscope having a display in figures 1-3 and column 1 line 61 – column 2 line 37, comprising bell 5, hollow tube assembly 2, cathode ray tube 10 and earpieces 19 which reads on "A hybrid stethoscope comprising a bell placeable by a user on a body site overlying an internal region to receive sounds emanating therefrom; a tubular line acoustically coupling the bell to earphones insertable in ears of the user to cause the user to hear said sounds; and a visual display module mounted on the bell and responsive to sounds received thereby and adapted to exhibit an analog waveform of the sounds whereby the user effectively sees as well as hears the sounds" wherein the bell 5 reads on "a bell placeable by a

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user on a body site overlying an internal region to receive sounds emanating therefrom”, the hollow tube assembly 2 and earpieces 19 read on “a tubular line acoustically coupling the bell to earphones insertable in ears of the user to cause the user to hear said sounds” wherein the tube assembly 2 reads on a “a tubular line” and the earpieces 19 read on “earphones” and cathode ray tube 10 reads on “a visual display module mounted on the bell and responsive to sounds received thereby and adapted to exhibit an analog waveform of the sounds whereby the user effectively sees as well as hears the sounds” wherein the analog waveforms are present on the cathode ray tube face 11 in figure 3.

Regarding **claim 3**, figure 2 illustrates the cathode ray tube 10 mounted on the rear side of the bell 5 which reads on “the module is mounted on a rear surface of the bell” wherein the cathode ray tube 10 reads on “the module” (visual display module).

### *Claim Rejections - 35 USC § 103*

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. **Claims 2, 4 and 5** are rejected under 35 U.S.C. 103(a) as being unpatentable over Marshall in view of Perin et al, US Patent 6,210,344 (hereafter referenced as Perin).

Regarding **claim 2**, Marshall also discloses pick-ups (microphones) 7, wires 8, and that the cathode ray tube 10 is mounted on bell 5 with a power source or battery unit 3 for powering the cathode ray tube 10 and amplifier 9. However, Marshall does not disclose that the visual

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display “module is a battery-powered self-sufficient unit”. In figures 1-3 and column 4 lines 22-54, Perin discloses a stethoscope comprising bell 22, diaphragm portion 24, transducer 36, tubing 42, earphones 44, and display unit 30. As specifically disclosed in column 4 lines 28-30, the display unit 30 is part of housing 28, which is connected atop bell 22. Column 4 lines 41-43 discloses a battery 40 (not shown) which is connected to the microprocessor 38 in the housing 28. Thus, Perin disclosed a visual display module which is a battery-powered self-sufficient unit wherein the display unit 30 reads on a “visual display” module and the display unit 30, including the associated transducer 36, can function apart from the passive stethoscope 20. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the Marshall apparatus to construct the cathode ray tube 10, battery unit 3, transducers 7, wires 8 and amplifier 9 as part of a battery-powered self-sufficient unit, per the teachings of Perin, for the purpose of providing a removable attachment for a conventional stethoscope and presenting the user with the flexibility of using the stethoscope without necessarily supplying a visual indication of the stethoscope sounds.

Regarding **claim 4**, the modified Marshall invention, per the teachings of Perin, as applied to claim 2, discloses a cathode ray tube in a self-sufficient battery-powered unit. The modified Marshall invention does not disclose that the visual display “module includes a liquid crystal display device to exhibit said waveform”. Perin also discloses that the display unit 30 is a liquid crystal display in figure 4 and column 5 lines 51-52. It would have been obvious to one of ordinary skill in the art at the time of invention to substitute a liquid crystal display (LCD) for the cathode ray tube 10 in Marshall, per the teachings of Perin, for the purpose of providing a lighter and thinner display device.

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Regarding **claim 5**, at the time of invention, one of ordinary skill in the art would have known that in order for a visual display to show acoustic waveforms, the waveforms had to be acquired by some type of transducing means. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the microphones 7 of the modified Marshall apparatus (as applied to claim 4) to intercept “sounds received by the bell to produce an audio signal that is applied to the liquid crystal display device” for the purpose of supplying an electrical representation of the acoustic body waveforms for the user of the stethoscope.

8. **Claim 6** is rejected under 35 U.S.C. 103(a) as being unpatentable over Marshall in view of Perin as applied to claim 5 above, and further in view of the Applicant’s admitted prior art (APA). The combination of Marshall and Perin does not disclose that “the tubular line functions as a low pass filter to filter out high-frequency components of the sounds” however it was well known at the time of invention, as evidenced by the APA on page 2 of the specification, that conventional acoustic stethoscopes functioned as low pass filters, the filtering function being performed by the sound tubing connected to the earphones. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention that the hollow tube assembly 2 of the modified Marshall apparatus functioned as a low pass filter for the purpose of filtering out non-relevant high frequency sounds and passing only the relevant low frequency diagnostic body sounds.

9. **Claim 7** is rejected under 35 U.S.C. 103(a) as being unpatentable over Marshall in view of Perin further in view of the APA as applied to claim 6 above, and further in view of Semmlow et al, US Patent 5,109,863 (hereafter referenced as Semmlow). The combination of Marshall, Perin and the Admitted Prior Art does not disclose “the microphone of the module is sensitive to

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said high-frequency components which are included in said audio signal". Semmlow discloses a diagnostic system for detecting coronary artery disease comprising a transducer (microphone 1), amplifier 2, signal processor 7 and display terminal 14 in figure 1. In the abstract, Semmlow discloses that the transducer provides high sensitivity at high frequencies for detecting coronary artery disease. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the combination of Marshall, Perin and the APA by using a microphone sensitive to high frequencies, per the teachings of Semmlow, for the purpose of improving the diagnostic capabilities of the stethoscope with respect to body sounds.

10. **Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over Marshall in view of Applicant's Admitted Prior Art (APA). Marshall discloses a stethoscope comprising bell 5, hollow tube assembly 2, cathode ray tube 10 (visual display module) and earpieces 19 wherein the cathode ray tube 10 is mounted on the bell 5. Marshall does not disclose that "the bell is double headed, opposing heads of the bells being joined at a junction to which said module is laterally attached." On page 2, third paragraph of the specification, the APA discloses a prior art acoustic stethoscope having a double-headed bell which functions like a conventional stethoscope. The double-headed bell would be naturally joined at a junction. The visual display module in the Marshall apparatus is mounted on a rear surface of the bell of a stethoscope as illustrated in figure 2 with the intention of providing electronic display capability while retaining the conventional use of a stethoscope, as disclosed in column 1 lines 32-36. Since it was well known to have a stethoscope with a double-headed bell, as pointed out by the Applicant, one of ordinary skill in the art would have realized without undue experimentation that the only place to mount a visual display unit to the bell on such a stethoscope without disturbing its conventional



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use would be on its side. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the Marshall apparatus by substituting a double-headed bell, a well known component for stethoscopes as taught by the Applicant, and attaching the cathode ray tube 10 (visual display unit) at the side of the double headed bell, for the purpose of increasing the utility of the stethoscope yet still providing a visual indication of body sounds.

11. **Claim 9** is rejected under 35 U.S.C. 103(a) as being unpatentable over Marshall in view of Scalise et al, US Patent 5,812,678 (hereafter referenced as Scalise). Marshall does not disclose that the visual display “module includes a transmitter to convey said audio signal to an external monitor adapted to exhibit said waveform and to manipulate said waveform to effect measurements which aid in an analysis thereof.” Scalise discloses a stethoscope system in figure 9a comprising sensor subsystem 404, receiver 418, and recording device 420. Column 12 lines 54-59 disclose that sensor subsystem 404 has the same function of the first module of figure 5a (element 200) which comprises an acoustic collecting chamber, amplification electronics and a transmitter for transmitting modulated body sounds (see column 10 lines 19-29). The body sounds are transmitted to a receiver, which, in the case of figure 9a, is receiver 418. Column 13 lines 1-4 disclose that the recording device 420 is capable of analyzing and playing back the body sounds from sensor subsystem. Thus, Scalise discloses a module which “includes a transmitter to convey said audio signal to an external monitor adapted to exhibit said waveform and to manipulate said waveform to effect measurements which aid in an analysis thereof” whereby sensor subsystem 404 reads on “module includes a transmitter to convey said audio signal” and recording device 420 reads on “an external monitor adapted to exhibit said waveform” whereby the recording device 420 can playback (manipulate) and analyze the sounds.

It would have been obvious to one of ordinary skill in the art at the time of invention to modify Marshall to include a transmitter in the visual display device and incorporate an external monitor, as disclosed by Scalise, for the purpose of recording and playing the sounds for subsequent analysis.

12. **Claim 10** is rejected under 35 U.S.C. 103(a) as being unpatentable over Marshall in view of Scalise as applied to claim 9 above, and further in view of Pfohl, US Patent 4,981,139 (hereafter referenced as Pfohl). The combination of Marshall and Scalise do not disclose the “transmitter is a microwave transmitter and said monitor is provided with a microwave receiver to receive and demodulate the transmission to derive the audio signal therefrom.” In column 13 lines 15-20, Scalise suggests that any transmitter-receiver combination and modulation format is possible for implementation of the transmitter 404 and receiver 418. Pfohl, in figure 1, discloses a vital signs monitoring and communication system comprising an esophageal stethoscope 14, chest sounds sensor 18, blood pressure cuff 24 and control unit 12. Figure 2 illustrates the control unit 12, which contains an infrared transmitter 92 for transmitting audio to a portable receiver 32, as described in column 3 lines 26-68. The audio transmitted is the vital signs (chest sounds, blood pressure and esophageal sounds) of a patient. Column 8 lines 3-29 discloses that the carrier signal (light waves) for the communication between the transmitter and receiver fall within the range of microwaves. Therefore, Pfohl discloses a microwave transmitter and a microwave receiver to receive and demodulate the transmission to derive the audio signal. Specifically, column 8 lines 22-25 disclose that microwaves are used to eliminate interference with electronic equipment. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the combination of Marshall and Scalise to use microwave

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transmission and reception for the audio signals sent from the stethoscope visual display module to an external monitor, per the teachings of Pfohl, for the purpose of providing a safe communication environment wherein crucial hospital equipment is not affected by stethoscope sound transmission.

13. **Claim 11** is rejected under 35 U.S.C. 103(a) as being unpatentable over Marshall in view of Scalise. Marshall does not disclose “an intercommunication system comprising a plurality of hybrid stethoscopes...provided with means intercoupling the visual display modules whereby the waveform produced by any module in the system is exhibited in other modules thereof”. In figure 5a Scalise discloses a stethoscope system comprising sensing module 200 and receiver module 202 attached to stethoscope 204 whereby the sensing module 200 is used to detect body sounds and transmit the sounds to the receiver module 202. Column 9 line 57 – column 10 line 66 discloses that the sensing module 200 can transmit to more than one receiver module 202 in the event that more than one medical expert is required to simultaneously monitor and diagnose a patient’s condition. Thus, Scalise discloses an intercommunication system comprising a plurality of stethoscopes wherein the waveform produced in the sensing module 200 (which can be attached to a stethoscope) can be exhibited in the receiver modules 202 (other stethoscopes). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Marshall and incorporate a system of stethoscopes having receivers and transmitters wherein the waveform on the visual display of one stethoscope can be exhibited in the other stethoscopes, per the teachings of Scalise, for the purpose of providing the waveform to a plurality of medical staff members and increasing the likelihood of a quick and correct assessment of a patient.

14. **Claim 12** is rejected under 35 U.S.C. 103(a) as being unpatentable over Marshall in view of Scalise as applied to claim 11 above, and further in view of Pfohl. The combination of Marshall and Scalise do not disclose the "a microwave transmitter to transmit the waveform to the other modules, and a receiver to receive the transmitted waveform." In column 10 lines 20-28, Scalise suggests transmission methods for the sensing module 200, including infrared. Pfohl, in figure 1, discloses a vital signs monitoring and communication system comprising an esophageal stethoscope 14, chest sounds sensor 18, blood pressure cuff 24 and control unit 12. Figure 2 illustrates the control unit 12, which contains an infrared transmitter 92 for transmitting audio to a portable receiver 32, as described in column 3 lines 26-68. The audio transmitted is the vital signs (chest sounds, blood pressure and esophageal sounds) of a patient. Column 8 lines 3-29 discloses that the carrier signal (light waves) for the communication between the transmitter and receiver fall within the range of microwaves. Therefore, Pfohl discloses a microwave transmitter and a microwave receiver to receive and demodulate the transmission to derive the audio signal. Specifically, column 8 lines 22-25 disclose that microwaves are used to eliminate interference with electronic equipment. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the combination of Marshall and Scalise to use microwave transmission and reception, per the teachings of Pfohl, for the audio signals sent between stethoscope visual display modules, for the purpose of providing a safe communication environment wherein crucial hospital equipment is not affected by stethoscope sound transmission.

15. **Claims 13 and 14** are rejected under 35 U.S.C. 103(a) as being unpatentable over Marshall in view of Perin as applied to claim 5 above, further in view of Scalise.

Regarding **claim 13**, the combination of Marshall and Perin does not disclose “a system for conducting a stethoscopic examining using a hybrid stethoscope...in which the audio signal yielded by the microphone in the module is transmitted to a remote station at which it is recorded.” Scalise discloses a stethoscope system in figure 9a comprising sensor subsystem 404, receiver 418, and recording device 420. Column 12 lines 54-59 disclose that sensor subsystem 404 has the same function of the first module of figure 5a (element 200) which comprises an acoustic collecting chamber, amplification electronics and a transmitter for transmitting modulated body sounds (see column 10 lines 19-29). The body sounds are transmitted to a receiver, which, in the case of figure 9a, is receiver 418. Column 13 lines 1-4 disclose that the recording device 420 is capable of recording, analyzing and playing back the body sounds from sensor subsystem. Thus, Scalise discloses a system for conducting a stethoscopic examination in which an audio signal yielded by the microphone in the module is transmitted to a remote station where it is recorded, whereby the sensor subsystem 404 reads on “an audio signal yielded by the microphone in the module is transmitted” and recording device 420 reads on “a remote station at which it is recorded”. It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate a remote station with a recorder, per the teachings of Scalise, in the combination of Marshall and Perin for the purpose of generating a permanent entry of the body sounds of a patient for later analysis.

Regarding **claim 14**, it was well known at the time of invention that stethoscopes were used as detect body sounds, specifically those of the heart and lungs, therefore, it would have been obvious to one of ordinary skill in the art at the time of invention that “the body site at

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which the bell is placed is the chest of the patient, and the resultant audio signals are breathing sounds” for the purpose of diagnosing breathing problems emanating from the chest.

16. **Claim 15** is rejected under 35 U.S.C. 103(a) as being unpatentable over Marshall in view of Perin, further in view of Scalise as applied to claim 13 above, and further in view of Bredesen et al, US Patent 5,218,969 (hereafter referenced as Bredesen). The combination of Marshall, Perin and Scalise does not disclose “the system is selectively operable in several modes, each of which depends on the body site on which the bell is placed, said module including means to preface the signal yielded by the microphone in a selected mode with a code signal identifying the mode.” In figure 1 and column 2 line 66 – column 3 line 23, Bredesen discloses a stethoscope comprising bell 106, earpieces 104 and display 102 having a keyboard 110 wherein the body sounds detected by the bell 106 are digitized and displayed on LCD graphics panel display 102. Also disclosed in figure 4 is the microprocessor routine performed by the stethoscope which includes step 412 which queries for the depression of the mode key as there are several modes of operation (cardiac, lungs, bruits). Figure 6 illustrates the sternum diagram 601 displayed on the LCD display 102 during examination of heart sounds in the cardiac mode and column 34 lines 44-65 and figure 10 disclose a lung display 1001 and 1002 which is exhibited on the LCD 102 in the lung mode of operation. Thus, Bredesen discloses a system which is operable in several modes, each of which depends on the body site on which the bell is placed and a diagram which prefaces the signal yielded by the stethoscope in a selected mode whereby the diagram represents a code signal identifying the mode. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the combination of Marshall, Perin and Scalise to include a mode diagram as a code signal identifying the mode, as taught by

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Bredesen, for the purpose of later identification of the body signals and the avoidance of confusion regarding the origin of the body signals.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Pendleton whose telephone number is (703) 305-9509. The examiner can normally be reached on M-F 7-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Forester W. Isen can be reached on (703) 305-4386. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



btp

**BRIAN PENDLETON  
PATENT EXAMINER**